

Rebalancing Evidence-Based Healthcare: The Central Role of Patients and Consumers

A Resource from The National Working Group on Evidence-Based Health Care
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Over the past few years, payers, academics and policymakers are increasingly focused on developing better information for clinical decision-making, ensuring the translation of this research to a variety of audiences, including patients, and considering changes to the delivery of healthcare services to align payment with what is thought to be best practice. These efforts have recently evolved into several policy proposals to increase the federal funding and leadership for the development of comparative effectiveness research. A common theme in these proposals is the desire to influence health care in a manner that is best for the patient. Ironically, the discussion, planning, and efforts led by payers, academics, and policymakers often miss opportunities to integrate the viewpoint of their most important audience, patients.

In this era of consumer direction and empowerment, it seems incongruent to continue to view patients as the audience, rather than as a partner in developing solutions that will improve the quality and value of care delivered. The National Working Group on Evidence-Based Health Care (The Working Group) emerged in early 2006 as an effort to expand the understanding and engagement of patients/consumers, advocates, providers and researchers in initiatives and dialogue related to evidence-based healthcare. Through information exchange and engagement in public dialogue, the Working Group has emphasized the importance of balancing an understanding of scientific research with real-world clinician expertise and particularly the perspectives and preferences of the patient/consumer.

The Working Group strives to empower patients and consumers by involving them in designing and prioritizing of research, as well as reviewing evidence and contributing to its translation, dissemination, implementation, and evaluation. The Working Group supports including diverse stakeholders' perspectives in the conversations currently transpiring in the public and private sector on generating more evidence to make health care decisions, developing best practices and care guidelines, and creating incentives for more value-based healthcare.

This paper outlines the Working Group's call to action for the evidence-based healthcare community to ensure patient and consumer involvement, principles for patient/consumer inclusion, and a checklist for ensuring the patient/consumer perspective is a part of the evidence-based healthcare equation.

For more information about The National Working Group on Evidence-Based Health Care please visit www.evidencebasedhealthcare.org.



Call to Action

As evidence-based healthcare continues to evolve, so do opportunities to involve patients/consumers in its research, dissemination, and application efforts. While this paper offers a point-in-time list of suggested mechanisms for inclusion, there are action items for all stakeholders.

- All entities and actors participating in dialogue and activities related to evidence-based healthcare should identify processes in place and those that can further promote and enable patient/consumer inclusion.
- Governments must ensure that their processes are transparent and that patient/consumer representation is both actively pursued and financially supported.
- Industry sectors must ensure that their research is transparent to the patient/consumer community, and that they include patient/consumer representation or participation in the discovery and development of emerging technologies.
- Payers must ensure that applying population-based research does not hinder practitioners' ability to deliver individually-appropriate healthcare services and treatments.
- All funders must incorporate patient/consumer preferences into their priorities and ensure that the research they fund answers the most important patient/consumer questions.
- Researchers must ensure that research they conduct integrates the patient/consumer perspective in the development of research study designs, including defining study samples representative of real-world patients, choosing patient-centered outcome measures and incorporating patient preferences.
- Providers/caregivers should educate themselves about evidence-based research in their field and encourage professional societies and other educational bodies to develop dissemination tools and resources to support such awareness.
- Providers/caregivers must also collaborate with consumers/patients to incorporate patient preferences and goals in combination with a review of the available evidence for decision-making.
- Patient/consumer organizations must make their involvement in evidence-based healthcare a priority issue by educating their constituencies about evidence-based healthcare and engaging them locally and nationally.
- Individual patients/consumers must view all information in the healthcare marketplace with a critical eye and incorporate such information with their own experiences, values, and goals to engage in an active decision-making partnership with their caregivers.



Putting Patients/Consumers First: Inclusion as a Partner, Not Only as the Audience

Inclusion in all processes is fundamental to ensuring that solutions to healthcare reform will include the relevant and valuable perspectives of patients/consumers. At a minimum, adequate funding, training, and support must be available to make such representative participation happen. The following section details specific means to include patients/consumers in the governance and operations of any comparative effectiveness research entity.

Governance and Accountability

Patients/consumers are a vital partner in shaping the development and use of comparative effectiveness research. The following recommendations are initial steps to ensure that any comparative effectiveness research organization appropriately integrates the viewpoints of patients/consumers.

- Ensure that advisory and active voting roles within government entities, technology assessment institutions, and industry and payer organizations are held by diverse patients/consumers and patient representative organizations.
- Promote and ensure inclusion of patients/consumers on institutional review boards (IRBs) and other research oversight mechanisms, such as FDA review panels.
- Ensure that patients and consumers are on peer review panels to review all draft research findings, not just offer public comments.
- Provide a more continuous process for soliciting patient/consumer input on all processes related to the funding and conduct of research, rather than internet only, two-week comment periods.
- Ensure equal time for public comment by patients/consumers and/or representative organizations in public forums, such as hearings.
- Tap into existing patient/consumer contacts and networks to identify future and additional key consumer/patient constituencies and experts.

Prioritization of Research

A stronger role for patients/consumers at the advent of new research will benefit the evidence generation enterprise. Patients and consumers should be involved in several ways.

- Involve patients/consumers in identifying further unanswered questions or research gaps that can provide a “feedback loop” to the research development phase.
- Promote patient and consumer participation in pre-clinical research focus groups that identify targets for new research, including identification of evidence gaps, and clinical or quality of life endpoints.
- Invite and incorporate patient/consumer input in defining and prioritizing post-market research needs and methods.
- Engage patients/consumers in defining health services research agendas, as well as defining methods to evaluate the impact of system changes brought about by the application of evidence into practice.



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Development of Research Studies

Current proposals to increase public and private payer's investments in comparative effectiveness research have offered limited opportunity to include the patient/consumer perspective. The few opportunities that exist often solicit input from the same consumer organizations. A broader representation of the patient perspective is needed.

- Actively involve patients/consumers and representative organizations in comparative research in defining key questions, and research methodologies.
- Require clinical research to measure consumer-focused endpoints, such as quality of life measures and functionality.
- Include patients/consumers on pre-clinical and post-market review panels within government regulatory bodies to ensure critical assessment of research and pinpoint goals and outcomes of importance to real-world patients.
- Provide incentives for research organizations to demonstrate methods for including patient/consumer perspectives.

Translation and Dissemination

Patient/consumer outcome and treatment preferences are central to effective implementation of clinical decision-making. A clear understanding of patient/consumer experiences, needs, expectations, and development of effective consumer communication techniques are essential to developing usable information for patients/consumers. The following recommendations are intended to ensure that consumers are at the heart of translating research-derived information into action.

- Actively reach out to and engage patients/consumers to test key findings derived from evidence development, and include those perspectives in the translation of research.
- Consistently use patients/consumers to translate research for a lay audience and review of draft translational materials, such as through focus groups, and peer review identification of optimal methods and strategies for communicating.
- Involve patients/consumers in identifying key questions and/or action steps consumers can use to implement evidence-based findings into their healthcare decision-making. Conduct patient/consumer focus groups to draw input on barriers to implementing research into consumer practice/action (e.g., what are different ways patients/consumers will incorporate research information into personal discussions, and clinical interactions).
- Involve patients/consumers in developing training materials, media, or other educational products for targeted audiences.
- Use patients/consumers to identify messaging gaps, health literacy needs, or areas for further research.
- Seek input from patients/consumers on culturally appropriate messages and approaches to translating research for their particular cohort (disease, ethnicity, or age groups).
- Include patients/consumers in identifying methods, channels, tools, and networks to disseminate research effectively and efficiently.



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- Include patients/consumers in identifying key segments and special target populations.
- Create partnerships with patient/consumer organizations to optimize dissemination networks and methods (e.g. allow cross-linkage on materials and websites to patient/consumer organizations with expertise in a specific condition to maximize patient/ consumer opportunity to seek further information).
- Train and invest in resources to sustain patients/consumers as peer educators about research information as they are the definitive “trusted source.”
- Develop public-private partnerships with patients/consumers and representative organizations for public education and media methodologies for disseminating research.

Implementation

The final stage for evidence-based research is its implementation into practice. However, this stage is also given the least attention; unintended consequences may result for patients/consumers, such as less choice, less involvement in treatment decisions, and less access to potentially life-enhancing therapies and interventions. Stakeholders at all levels must invest more on the implementation of evidence, in both focused dialogue about how implementation should occur, as well as resources to ensure that implementation occurs in the best interest of the patient/consumer.

- Ensure transparency of evidence-based decision-making processes and criteria, such as in determining coverage and payment.
- Include voting patient/consumers and representative organizations on advisory panels that inform coverage and reimbursement policy and the development of quality measures and pay-for-performance systems.
- Institute active monitoring, research, and analysis to track patient health outcomes and cost-offsets and identify any access to care issues that result from policy changes.
- Emphasize distinct evaluation of subpopulations, including chronic illness, cultural, and socio-economic cohorts.
- Include patients/consumers in stakeholder dialogue with decision-making entities (public and private) to identify key lessons from evidence development activities, identify targets for policy change, map intended and unintended consequences and formulate evaluation plans to monitor impact based on outcomes that are defined with patients/consumers.



A Checklist for Balanced Evidence-Based Healthcare

This tool helps patient/consumer organizations evaluate the public and private-sector initiatives in evidence-based healthcare to ensure that such processes meet our call to action. It also is an important tool for all stakeholders to review their efforts and explore opportunities for improvement. Transparency and inclusion involves patient/consumer participation in the following areas:

Research Design and Prioritization

- Focus groups and dialogue with researchers about research priorities/gaps, including post-market research and evaluation needs
- Focus groups and dialogue with researchers about designing clinical research targets/endpoints
- Focus groups and dialogue with researchers about key question development for comparative effectiveness research
- Patient/consumer participation in research advisory or oversight bodies
- Patients/consumer advisory roles within government entities, technology assessment institutions, and industry and payer organizations

Evidence Review

- Patient/consumer participation (including public comment, targeted advisory panels, dialogue) regarding prioritization of conditions and treatment approaches to be studied
- Contribution and dialogue to key question development
- Review and focus group/targeted interview input on draft comparative effectiveness reports
- Patient perspectives on research findings and identification of unanswered questions; real world relevance
- Participation in research review for approval and coverage decision-making

Translation and Dissemination

- Focus groups of consumers for targeted patient/consumer populations (representing geographic, racial/ethnic/cultural, and socio-economic cohorts)
- Advisory review of materials by representative sample of relevant patient/consumer organizations
- Consumer organizations as partners for dissemination

Implementation

- Identification of unanswered questions/research gaps
- Identification of key consumer/patient constituencies and additional experts for dissemination
- Evaluation of research findings and effects on payer, patient, and provider behavior through monitoring impact on patient health/outcomes/access to care

Other

- Meaningful roles at public forums, hearings, or expert groups
- Voting roles on advisory panels, and oversight bodies
- In public record through electronic and/or print mechanisms

